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Re-evaluation Note REV2018-13

Re-evaluation Project Plan for Azoxystrobin

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Background

In Canada, azoxystrobin is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

Azoxystrobin is an agricultural fungicide registered for use against foliar, seed-borne and soil-borne diseases on a variety of field crops, fruits, vegetables, specialty crops, greenhouse ornamentals, outdoor ornamentals, and turf. It is also registered for storage disease control on harvested potatoes. As of 15 May 2018, there are eight technical, one manufacturing concentrate and 26 commercial class end-use products containing azoxystrobin registered in Canada.

Under the authority of section 16 of the *Pest Control Products Act*, the registrants of azoxystrobin were notified of the initiation of the re-evaluation of azoxystrobin. Following this, the registrants of the technical grade active ingredient azoxystrobin in Canada indicated support of all uses included on the labels of end-use products in Canada.

The re-evaluation project plan below outlines the timeline, the anticipated areas of focus for the risk assessments, and the data requirements for the re-evaluation of azoxystrobin.

Re-evaluation Project Plan

Anticipated Re-evaluation Timeline

The re-evaluation of azoxystrobin is defined as a Category 1 as described in Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for azoxystrobin is anticipated to be published for consultation by November 2019. The re-evaluation timeline may be updated if, during the risk assessment, the PMRA identifies additional areas of focus that should be considered.

Human Health Risk Assessment

New assessments will be conducted for toxicology, dietary exposure and occupational exposure (seed treatment). Existing assessments with minor updates are considered to be adequate to support the re-evaluation of azoxystrobin for the other aspects of human health assessment.

Environmental Risk Assessment

New assessments will be conducted for environmental fate, water modelling and environmental exposure.

Value

The value of azoxystrobin will be considered. The viability of alternatives will be examined for certain uses if risks of concern requiring mitigation are identified.

Data Requirements

The PMRA has identified the need for the technical registrants to provide data for azoxystrobin related to toxicology, environmental fate and ecotoxicology. Available data have been submitted to the PMRA. Other studies have to be generated and the registrant has committed to provide these studies to the PMRA by February 2019. A summary of the data call-in is found in the PMRA's Public Registry. For a list of data categories that have been required, see Appendix I. In addition, information regarding the registered use pattern has been requested and received from the registrants, to inform the risk assessments.

Additional Information

PMRA documents can be found in the Pesticides section of Canada.ca. The PMRA documents are also available through the Pest Management Information Service:

Phone:	1-800-267-6315	within Canada, or
	1-613-736-3799	outside Canada (long distance charges apply)
Fax:	1-613-736-3798	
E-mail:	hc.pmra.info-arla.sc@canada.ca	

Appendix I Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of Azoxystrobin

I. Toxicology Data

DACO	Title
4.2	**Acute Studies - TGAI**
4.2.1	Acute Oral
4.2.2	Acute Dermal
4.2.3	Acute Inhalation
4.2.4	Primary Eye Irritation
4.2.5	Primary Dermal Irritation
4.2.6	Dermal Sensitization
4.2.9	Other Acute Studies
4.3	**Short-term Studies - TGAI**
4.3.6	Short-term Inhalation (90-day)
4.5	**Special Studies - TGAI**
4.5.4	Genotoxicity: Bacterial Reverse Mutation Assay
4.5.5	Genotoxicity: In vitro Mammalian Cell Assay
4.5.7	Genotoxicity: In vivo Cytogenetics
4.5.9	Metabolism/Toxicokinetics in Mammals (laboratory animals)
4.5.12	Acute Neurotoxicity (rat)
4.5.13	90-day Neurotoxicity (rat)
4.8	Other Studies/Data/Reports
12.5.4	Foreign Reviews of Toxicology

II. Environmental Fate Data

DACO	Title
8.2.3.4	**Biotransformation in Soil**
8.2.3.4.2	Aerobic Soil 20°–30°C

III. Ecotoxicology Data

DACO	Title
9.2.4	**Bees/Pollinators**
9.2.4.4	Bee Adult Chronic Toxicity
9.4	**Non-Target Marine Invertebrates**
9.4.2	Acute (Crustacean)
9.4.4	Mollusk Shell Deposition
9.4.5	Chronic (Mollusk or Crustacean)
9.5	**Fish**
9.5.2	**Acute Studies**
9.5.2.4	Marine/Estuarine Fish
9.8	**Non-Target Plants**

DACO	Title
9.8.3	Marine Algae